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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/163,199	09/30/98	FUKUSHIMA	H 04783/026001

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HM12/1113

EXAMINER

GARCIA, M

ART UNIT	PAPER NUMBER
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1627

12

DATE MAILED:

11/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File copy

Office Action Summary

Application No.
09/163,199

Applicant(s)

Fukushima et al

Examiner
Maurie E. Garcia, Ph. D.

Group Art Unit
1627



☒ Responsive to communication(s) filed on Aug 16, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-26 is/are pending in the application

Of the above, claim(s) 3-6, 9-17, and 20-26 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, 7, 8, 18, and 19 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 & 6

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. Applicant's Response filed August 16, 2000 (Paper No. 11) is acknowledged. No claims were amended, cancelled or added. Therefore, claims 1-26 are pending.

Restriction/Election

2. Applicant's election with traverse of Group I (Claims 1-4, 7, 8 and 18-20) is acknowledged as well as the election of species (Species 1, electro-conductive polymer). The traversal is addressed below.

3. Applicant's arguments are not found persuasive. The examiner did set forth a prima facie case for Restriction as delineated in MPEP § 806.05 and Applicant did not distinctly and specifically point out the supposed errors. Applicants instead traverse the Restriction Requirement with respect to the separation of the all of the claims, stating that "there is convergent subject matter" and that combined search and examination "should be coextensive" (Response, page 1). However, the examiner maintains that the inventions are distinct for the reasons set forth in the previous Restriction Requirement, see particularly paragraphs 3-5.

4. Also as stated previously, it is the examiner's position that the inventions of Groups I-III have acquired a separate status in the art as shown by their **different classification** and/or

divergent subject matter. The different methods and products claimed would require completely different searches in the patent and non-patent databases. Contrary to applicant's assertion, the examiner maintains that there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden. The requirement is still deemed proper and is therefore made FINAL.

5. Because applicant did not distinctly and specifically point out the supposed errors in species election, this election has been treated as an election without traverse (MPEP § 818.03(a)) with respect to the species.

6. Claims 5, 6, 9, 10-17 and 21-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions, the requirement having been traversed in Paper No. 11.

7. Claims 3, 4 and 20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species. Election was made **without** traverse in Paper No. 11.

8. Therefore, claims 1, 2, 7, 8, 18 and 19 are examined on the merits.

Priority

9. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

10. This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed. The drawings are objected to by the draftsman under 37 C.F.R. 1.84 or 1.52. See PTO-948 for the details of these objections. Correction of the noted defects in the drawings can only be deferred until the application is allowed by the examiner.

Information Disclosure Statement

11. The information disclosure statement filed March 9, 1999 fails to *fully* comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language. It has been placed in the application file, but the information referred to therein with respect to the document EP 0 469 445 has not been considered. This document is not in English and no English language Abstract or any other documentation was provided.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A. The term "arbitrarily" in claim 1 is a relative term which renders the claim indefinite.

The term "arbitrarily" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

- B. The term "micro-dots" in claim 1 is a relative term which renders the claim indefinite.

The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. That is, what is the size of such "micro-dots"?

- C. The term "high-density" in claim 19 is a relative term which renders the claim

indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. That is, how "high" must the density of electrodes be to be considered "high-density"?

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

15. Claims 1, 2, 7, 8, 18 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Plotkin et al (On PTO-1449).

Plotkin et al disclose a micro array of disposable electrodes that are prepared using an ink-jet (see page 2188). Specifically, the ink-jet dispenses small amounts (“micro-dots”) of a conductive reagent dissolved in a solvent in a high density format (2mm x 3mm array), thus reading on the limitations of claims 1, 2, 18 and 19. The electrodes have a transducing element of mercury on the carbon electrode (see page 2188, 1st column, bottom).

16. Claims 1, 2, 7, 8, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Newman et al (On PTO-1449).

Newman et al disclose ink-jet printing as a manufacturing technique for glucose biosensors (see Abstract). Screen printed carbon electrodes were used as the basis for

the sensor (see page 14), with a conducting mediator (TTF) dissolved in a solvent then printed thereon in a high density format of 16 x 21 droplets (see page 15, "Preparation"), thus reading on the limitations of claims 1, 2, 18 and 19. The electrodes have a transducing element of TTF on the carbon electrode (see pages 14-15 of the reference). The ink-jet dispenses small amounts ("micro-dots") of the conductive reagent, reading on the limitations of the instant claims.

Status of Claims/ Conclusion

17. No claims are allowed.

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,200,051 Cozzette et al; Discloses microfabrication of electronic devices adapted for the analyses of biologically significant analytes (see Abstract and claim 1).

US 5,063,081 Cozzette et al; Discloses a plurality of microfabricated sensing devices (see Abstract and claim 1).

US 5,554,339 Cozzette et al; Discloses microfabrication of electronic devices adapted for the analyses of biologically significant analytes (see Abstract and claim 1).


US 5,250,439 Musho et al; Discloses conductive sensor and use in diagnostic assay (see Abstract and claim 1).

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-

0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.
November 5, 2000


DR. JYOTHSNA VENKAT PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600